510(k) Summary or Statement

K073372

DEC 07 2007

Submitted by: SystemsOne, LLC
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Regulatory and Clinical Research Institute, Inc.
5353 Wayzata Boulevard, Suite 505
Minneapolis, MN 55416

Summary Date: November 8, 2007

Proprietary Name: Electrophysiology Systems Integrator (EPSI)

Common Name: Display, Cathode-Ray, Medical

CFR Reference: 21CFR§870.2450

Class: II

Product Code: DXJ

Equivalent Marketed Device(s): CIC Pro Clinical Information Center Central Station, GE Medical, K053356

HP CareVue 9000, Hewlett-Packard, K992636

Medical Multi-Disclosure Workstation, SpaceLabs, K962811

Device Description: The EPSI is a video integration system that uses a video splitter to take the original source image from a device and send it out to a variety of locations, such as the original intended monitor, a hemodynamics recording system in the control room, etc. The split image is then sent into the EPSI system (Flat Panel LCD monitor) and a Keyboard-Video-Mouse (KVM) switch. The display on the LCD at any time is controlled by a touchpad panel.

Intended Use: The EPSI system is intended to be used by health care professionals to integrate the video outputs from several commercially-available instruments into a single video display. These instruments may be commonly found in the electrophysiology laboratory, cardiac catheterization laboratory or where special or general fluoroscopy is used. Control of the video sources is accomplished using a touchpad device.

Technological Characteristics: The EPSI system integrates multiple technologies available "off-the-shelf" from different manufacturers so they can be easily managed with less equipment. The system allows for numerous overlapping images from existing medical instrumentation to be viewed on the same large screen; records and archives data from multiple sources that are accessible on a single station and provides easy retrieval and control of all onscreen data via touchpad controls.

Substantial Equivalence Rationale: Based on an analysis of the technology and intended use of the predicate devices cited, SystemsOne, LLC, believes that the EPSI system is substantially equivalent to several devices currently on the market.

Test Conclusions: SystemsOne, LLC, has conducted extensive testing of the EPSI system during development and installation. In addition, all electrical safety testing necessary to meet the IEC 60601-1 and its collateral standard IEC 60601-1-1 was completed by an experienced medical device electrical testing facility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 07 2007

SystemsOne, LLC
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K073372
Electrophysiology Systems Integrator (EPSI)
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode Ray Tube Display
Regulatory Class: Class II (two)
Product Code: DXJ
Dated: November 30, 2007
Received: December 3, 2007

Dear Mr. Job:

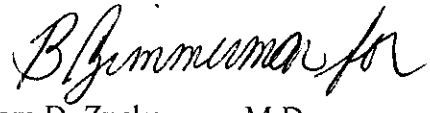
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number (if known): K073372 n/a

Device Name: **Electrophysiology Systems Integrator (EPSI)**

Indications for Use:

The EPSI system is intended to be used by health care professionals to integrate the video outputs from several commercially-available instruments into a single video display. These instruments may be commonly found in the electrophysiology laboratory, cardiac catheterization laboratory or where special or general fluoroscopy is used. Control of the video sources is accomplished using a touchpad device.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Hymmen

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number k073372